Working with your doctor is critical to ensure you get the most out of your treatment with LATUDA.

Keep in mind that starting any new medication may be a challenge. Work closely with your doctor until you find the right dose of LATUDA for you. Always check with your doctor before stopping your medication or changing the way you take it.

SOME QUESTIONS YOU MAY WANT TO ASK YOUR DOCTOR ABOUT LATUDA

• Is there a particular time of day I should take LATUDA?
• What are the benefits of LATUDA?
• What are the risks of LATUDA? How safe is it?
• What do I need to know about taking LATUDA in addition to my current medication(s)?
• What if I’m pregnant or planning to become pregnant?
• What side effects should I look out for?
• Do I need to take LATUDA with food?
• What else should I know about taking LATUDA?

Sharing as much information as you can may help your doctor create a treatment plan that works best for you. The following information is a good place to start.

• Symptoms
• Prior diagnosis
• Family history
• Current treatments
• Treatment goals

Other things I want to share with my doctor:

__________________________________________________________________________________________
__________________________________________________________________________________________
__________________________________________________________________________________________
__________________________________________________________________________________________

Are there any things that you feel may prevent you from getting the most out of your treatment with LATUDA? For instance, forgetting to take it as prescribed? Talk to your doctor or someone in your doctor’s office.

This discussion guide is designed to help you get more from your next doctor’s visit—or from an appointment or phone call you make especially to ask about getting the most from LATUDA. Remember that taking your medication exactly as directed is a critical part of your treatment.
LATUDA®

IMPORTANT SAFETY INFORMATION AND INDICATIONS FOR LATUDA

INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS; and SUICIDAL THOUGHTS AND BEHAVIORS

Increased risk of death in elderly people with dementia-related psychosis. Medicines like LATUDA can raise the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). LATUDA is not approved for the treatment of people with dementia-related psychosis.

Antidepressant medicines may increase suicidal thoughts or behaviors in some children, teenagers, and young adults within the first few months of treatment and when the dose is changed. Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Patients on antidepressants and their families or caregivers should watch for new or worsening depression symptoms, especially sudden changes in mood, behaviors, thoughts, or feelings. This is very important when an antidepressant medicine is started or when the dose is changed. Report any change in these symptoms immediately to the doctor.

LATUDA® may cause serious side effects, including:

- Stroke (cerebrovascular problems) in elderly people with dementia-related psychosis that can lead to death
- Neuroleptic malignant syndrome (NMS) is a serious condition that can lead to death. Call your health care provider or go to the nearest hospital emergency room right away if you have some or all of the following signs and symptoms of NMS: high fever, increased sweating, stiff muscles, confusion, or changes in your breathing, heart rate, and blood pressure
- Uncontrolled body movements (tardive dyskinesia). LATUDA® may cause movements that you cannot control in your face, tongue, or other body parts. Tardive dyskinesia may not go away, even if you stop taking LATUDA®. Tardive dyskinesia may also start after you stop taking LATUDA®
- Problems with your metabolism such as:
  - High blood sugar (hyperglycemia) and diabetes: Increases in blood sugar can happen in some people who take LATUDA®. Extremely high blood sugar can lead to coma or death. If you have diabetes or risk factors for diabetes (such as being overweight or a family history of diabetes), your health care provider should check your blood sugar before you start and during treatment with LATUDA®;
    - Call your health care provider if you have any of these symptoms of high blood sugar (hyperglycemia) while taking LATUDA®: feel very thirsty, need to urinate more than usual, feel very hungry, feel weak or tired, feel sick to your stomach, feel confused, or your breath smells fruity
  - Increased fat levels (cholesterol and triglycerides) in your blood
    - Weight gain. You and your health care provider should check your weight regularly during treatment with LATUDA®
  - Increased prolactin levels in your blood (hyperprolactinemia). Your health care provider may do blood tests to check your prolactin levels during treatment with LATUDA®. Tell your health care provider if you have any of the following signs and symptoms of hyperprolactinemia:
    - Females: absence of your menstrual cycle or secretion of breast milk when you are not breastfeeding
    - Males: problems getting or maintaining an erection (erectic dysfunction) or enlargement of breasts (gynecomastia)
  - Low white blood cell count. Your health care provider may do blood tests during the first few months of treatment with LATUDA®
  - Decreased blood pressure (orthostatic hypotension). You may feel lightheaded or faint when you rise too quickly from a sitting or lying position
  - Falls. LATUDA® may make you sleepy or dizzy, may cause a decrease in your blood pressure when changing position (orthostatic hypotension), and can slow your thinking and motor skills, which may lead to falls that can cause fractures or other injuries
  - Seizures (convulsions)
  - Problems controlling your body temperature so that you feel too warm. Do not become too hot or dehydrated during treatment with LATUDA®. Do not exercise too much. In hot weather, stay inside in a cool place if possible. Stay out of the sun. Do not wear too much clothing or heavy clothes. Drink plenty of water
  - Mania or hypomania (manic episodes) in people with a history of bipolar disorder. Symptoms may include: greatly increased energy, severe problems sleeping, racing thoughts, reckless behavior, unusually grand ideas, excessive happiness or irritability, or talking more or faster than usual
  - Difficulty swallowing

Do not drive, operate heavy machinery, or do other dangerous activities until you know how LATUDA® affects you. LATUDA® may make you drowsy.

Avoid eating grapefruit or drinking grapefruit juice while you take LATUDA® since these can affect the amount of LATUDA® in the blood.

Do not take LATUDA® if you are allergic to any of the ingredients in LATUDA® or take certain medications called CYP3A4 inhibitors or inducers. Ask your health care provider if you are not sure if you are taking any of these medications.

Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. LATUDA® and other medicines may affect each other, causing possible serious side effects. LATUDA® may affect the way other medicines work, and other medicines may affect how LATUDA® works. Your health care provider can tell you if it is safe to take LATUDA® with your other medicines. Do not start or stop any other medicines during treatment with LATUDA® without talking to your health care provider first.

Before taking LATUDA®, tell your health care provider about all of your medical conditions, including if you:

- have or have had heart problems or stroke
- have or have had low or high blood pressure
- have or have had diabetes or high blood sugar, or have a family history of diabetes or high blood sugar
- have or have had high levels of total cholesterol or triglycerides
- have or have had high prolactin levels
- have or have had low white blood cell count
- have or have had seizures
- have or have had kidney or liver problems
- are pregnant or plan to become pregnant. It is not known if LATUDA® will harm your unborn baby. Talk to your health care provider about the risk to your unborn baby if you take LATUDA® during pregnancy
  - Tell your health care provider if you become pregnant or think you are pregnant during treatment with LATUDA®
Do not start or stop any other medicines during treatment with LATUDA without talking to your health care provider first. This applies to prescription and over-the-counter medicines, vitamins, and herbal supplements. Tell your health care provider about all the medicines you take. Ask your health care provider if you are not sure if you are taking any of these medications.

Do not take LATUDA if you are allergic to any of the ingredients in LATUDA or take certain medications called CYP3A4 inhibitors or inducers. Ask your health care provider or pharmacist about the medicines you are taking, including over-the-counter medicines that contain ingredients that can interact with LATUDA.

You should not eat grapefruit or drink grapefruit juice while you take LATUDA since these can affect the amount of LATUDA in the blood.

LATUDA is a prescription medicine used:

- To treat adults and adolescents (13 to 17 years) with schizophrenia
- Alone to treat adults, children and teens (10 to 17 years) with depressive episodes that happen with bipolar I disorder (bipolar depression)
- With the medicine lithium or valproate to treat adults with depressive episodes that happen with bipolar I disorder (bipolar depression)

The most common side effects of LATUDA include:

- Adults with schizophrenia: sleepiness or drowsiness; restlessness or feeling like you need to move around (akathisia); difficulty moving, slow movements, or muscle stiffness; and nausea
- Adolescents (13 to 17 years) with schizophrenia: sleepiness or drowsiness; nausea; restlessness or feeling like you need to move around (akathisia); difficulty moving, slow movements, muscle stiffness, or tremor; runny nose/nasal inflammation; and vomiting
- Adults with bipolar depression: restlessness or feeling like you need to move around (akathisia); difficulty moving or slow movements; and sleepiness or drowsiness
- Children (10 to 17 years) with bipolar depression: nausea; weight gain; and problems sleeping (insomnia)

These are not all the possible side effects of LATUDA. For more information, ask your health care provider or pharmacist.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

**INDICATIONS**

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- If you become pregnant during treatment with LATUDA, talk to your health care provider about registering with the National Pregnancy Registry for Atypical Antipsychotics. You can register by calling 1-866-961-2388 or going to [http://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/](http://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/)
- Are breastfeeding or plan to breastfeed. It is not known if LATUDA passes into your breast milk. Talk to your health care provider about the best way to feed your baby during treatment with LATUDA

**SIDE EFFECTS**

LATUDA may cause movements that you cannot control in your face, tongue, or other body parts. Tardive dyskinesia may not go away, even if you stop taking LATUDA. Tardive dyskinesia may also start after you stop taking LATUDA.

- In more serious cases, LATUDA may cause movements that you cannot control in your face, tongue, or other body parts, as they may be signs of TD. TD may not go away, even if you stop taking LATUDA.
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- Patients on antidepressants and their families or caregivers should watch for new or worsening depression symptoms, especially sudden changes in mood, behaviors, thoughts, or feelings. This is very important when an antidepressant medicine is started or when the dose is changed. Depression and other serious mental illnesses are the most important causes of suicidal thoughts and behaviors.

Antidepressant medicines may increase suicidal thoughts or behaviors in some children, teenagers, and young adults within the first few months of treatment. Depression and other serious mental illnesses are themselves associated with an increase in the risk of suicide. Patients on antidepressants should be monitored closely.

**SUICIDAL THOUGHTS AND BEHAVIORS**

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